

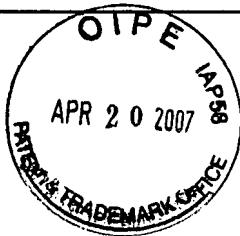
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April 20, 2007

Mail Stop Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: U.S. Application No. 09/394,745  
Filed: September 15, 1999  
Title: Nucleic Acid Molecules and Other Molecules Associated  
with Plants  
Applicants: Dane K. FISHER *et al.*  
Attorney Docket No.: 16517.280

Sir:

The following documents are forwarded herewith for appropriate action by the U.S.  
Patent and Trademark Office:

1. an Amended Appeal Brief under 37 C.F.R. § 41.37; and
2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to  
our courier.

In the event that extensions of time beyond those petitioned for herewith are necessary  
to prevent abandonment of this patent application, then such extensions of time are hereby  
petitioned. Applicants do not believe any fees are due in conjunction with this filing. However,  
if any fees are required in the present application, including any fees for extensions of time, then  
the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit  
Account No. 50-2387 referencing matter number 16517.280.

Respectfully submitted,

Gautam Prakash, Ph.D. (Reg. Agent No. 53,481)  
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David R. Marsh (Reg. Atty. No. 41,408)

Enclosure



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of:

Dane K. FISHER *et al.*

Application Serial No.: 09/394,745

Filed: September 15, 1999

Confirmation No.: 4816

Art Unit: 1637

Examiner: Young J. Kim

Attorney Docket No.: 16517.280

Title: Nucleic Acid Molecules and Other Molecules Associated with Plants

**Amended Appeal Brief under 37 C.F.R. § 41.37**

Mail Stop Appeal Brief – Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is an Appeal from the Final Rejection of claims in the above-captioned patent application. A Notice of Appeal was filed on November 16, 2006. An Appellants' Brief was filed on January 16, 2007, at which time the statutory fee for submitting an appeal brief was paid. This Amended Appeal Brief is submitted in response to the Office Communication mailed March 20, 2007, which alleged that the Appeal Brief was non-compliant with 37 C.F.R. § 41.37(c).

**1. Real Party in Interest**

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

## **2. Related Appeals and Interferences**

This application was previously appealed to the Board of Patent Appeals and Interferences, BPAI Appeal No. 2005-1340, and that proceeding may have a bearing on the Board's decision in the present Appeal. In addition, the Federal Circuit's decision in *In re Fisher* may also have a bearing on the Board's decision with regard to at least one of the grounds of rejection in the present appeal. Appellants submitted copies of the Board's decision in Appeal No. 2005-1340, and *In re Fisher*, 412 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005) as part of the Appeal Brief filed on January 16, 2007. In the interest of efficiency, Appellants are not providing additional copies herewith.

## **3. Status of Claims**

Claims 8 to 10 and 12 to 27 are pending. Claims 1 to 7 and 11 were canceled without prejudice to, or disclaimer of, the subject matter claimed therein, on October 10, 2000 and January 23, 2006. Claims 8 to 10 and 12 to 27 stand finally rejected under 35 U.S.C. § 112, first paragraph, and under 35 U.S.C. § 101. The Appellants appeal the rejections of claims 8 to 10 and 12 to 27.

## **4. Status of Amendments**

The Appellants have not filed any amendments subsequent to the final rejection dated August 16, 2006.

## **5. Summary of Claimed Subject Matter**

Independent Claim 8: The claimed subject matter of independent claim 8 is directed to a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules

where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the list of recited SEQ ID NOs, where the microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences. *Specification* at page 56, lines 5 to 17 and page 59, line 25 to page 62, line 7.

Independent Claim 14: The claimed subject matter of independent claim 14 is directed to a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of the recited SEQ ID NOs. *Specification* at page 56, lines 5 to 17 and page 59, line 25 to page 62, line 7.

Independent Claim 18: The claimed subject matter of independent claim 18 is directed to a microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group of the recited SEQ ID NOs. *Specification* at page 56, lines 5 to 17 and page 59, line 25 to page 62, line 7.

Independent Claim 22: The claimed subject matter of independent claim 22 is directed to a microarray comprising nucleic acid sequences obtained from maize, where the microarray comprises a substrate with a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group

of the recited SEQ ID NOs. *Specification* at page 56, lines 5 to 17 and page 59, line 25 to page 62, line 7.

Independent Claim 26: The claimed subject matter of independent claim 26 is directed to a substrate comprising nucleic acid sequences obtained from maize, where the substrate comprises a surface comprising at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group of the recited SEQ ID NOs. *Specification* at page 56, lines 5 to 17 and page 59, line 25 to page 62, line 7.

Independent Claim 27: The claimed subject matter of independent claim 27 is directed to a microarray for high-throughput monitoring of gene expression in a corn plant, where the microarray comprises a substrate with an array of at least 1000 oligonucleotide probes that hybridize to at least 1000 different nucleic acid molecules expressed by corn plant genes where at least 10% of the nucleic acid molecules are at least 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of the recited SEQ ID NOs, or the complements thereof, and where the microarray is effective for analyzing gene expression in corn lines including corn lines derived from the *Zea mays* genotype RX601. *Specification* at page 56, lines 5 to 17; page 59, line 25 to page 62, line 7; and page 92, lines 8 to 14.

A copy of the claims on appeal is attached hereto in the Claims Appendix.

## **6. Grounds of Rejection to be Reviewed on Appeal**

The grounds of rejection to be reviewed in this Appeal are:

- (a) pending claims 8 to 10 and 12 to 27 stand rejected under 35 U.S.C. §§ 101 and 112 because the claimed invention is allegedly not supported by either a specific and substantial asserted utility or a well established utility; and
- (b) pending claims 8 to 10 and 12 to 27 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement.

## **7. Argument**

### **A. Summary of Appellants' Position**

As the Supreme Court said in *Brenner v. Manson*, the “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility ... where specific benefit exists in currently available form.” 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Appellants have met their part of the bargain – they have disclosed microarrays and substrates comprising nucleic acid molecules expressed during anthesis in maize plants which, in their current form, provide at least one specific benefit to the public, for example use to monitor gene expression during anthesis. This benefit is specific, not vague or unknown, and it is a “real world” or substantial benefit. Because the claimed microarrays provide at least these benefits, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed microarrays for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has been met.

Furthermore, Appellant has provided an adequate description of the claimed microarrays having the recited nucleic acid molecules that demonstrates Appellant's possession of the claimed invention. The genera of claimed microarrays, for example, the genus of microarrays comprising the recited nucleic acid sequences, have been described by the recitation of common structural features, *e.g.*, the nucleotide sequence of SEQ ID NO: 5776, etc, which distinguishes molecules in the claimed genus from molecules not in the claimed genus. Because the specification demonstrates that Appellant had possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

#### **B. The Claimed Microarrays Have Utility**

The Examiner rejected pending claims 8 to 10 and 12 to 27 under 35 U.S.C. § 101, because the claimed invention allegedly "lacks patentable utility." *Final Office Action* mailed August 16, 2006 at page 2.

The specification provides a specific, substantial, and credible utility for the claimed microarrays. For example, the specification clearly asserts that the microarrays of the present invention can be used for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression of such genes. *See, e.g.*, specification at page 56, lines 5 to 17, page 59, line 18 through page 60, line 16, page 61, lines 4 to 10 and page 92, lines 8 to 14. The skilled artisan would have understood the utility of the claimed microarray based on such a disclosure. In addition, the claimed microarray allows for customization such that the skilled artisan can design the claimed microarrays to a given set of requirements determined by the artisan. One of

ordinary skill in the art would recognize that the claimed microarrays have utility, for example, to determine whether a biological sample contains maize nucleic acid sequences or hybridizing homologues upon reading the present specification. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The Examiner argues, however, that “[t]he claimed combination of nucleic acids comprised on a substrate or as a microarray is not supported by a substantial utility because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid.” *Final Office Action* at page 4. The Examiner asserts that “[u]nless the array, or the probes found on the array (i.e. nucleic acids), are specific for a certain disease, condition, or certain agronomically significant traits, the nucleic acids [are] only useful for conducting further research to find a substantial utility.” *Id.* at page 5. The Examiner appears to support this assertion by alleging that there “is no evidence that LIB189 is a subtractive library”, *Id.* at page 4, and that “there is no evidence that any of the nucleic acids comprised on the claimed microarray are expressed only at the time of ‘anthesis,’ only in leaf tissue, or only in *Zea mays* plant having the RX601 genotype.” *Id.* at page 5.

The Examiner has provided no support for the assertion that the genes can be expressed only during a given condition or must be specific to a certain disease or agronomic trait to satisfy the utility requirement. As previously stated, the claimed microarrays contain nucleic acid sequences from maize corresponding to genes expressed during anthesis. As such, the claimed microarrays can be used, for example, for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput moni-

toring of gene expression of such genes regardless of whether the sequences are expressed exclusively during anthesis.

The Examiner further appears to argue that all nucleic acid molecules are expressed during anthesis. The Examiner states that “[w]hile Applicants can state that the nucleic acids of the claimed microarray was expressed during anthesis, such statement can be made about any nucleic acid. All nucleic acids are expressed at some point.” *Id.* at pages 9 to 10. This statement is incorrect in at least two ways. First, not every nucleic acid is expressed during anthesis. Second, all nucleic acids are not expressed at some point. Indeed, the differential and non-expression of nucleic acids is an important component of gene regulation and differentiation of one organism from another. For instance it is a well-known fact that the DNA of human beings is 90+ percent identical to the DNA of chimpanzees. Differential and non-expression of genes is a critical reason why human beings are different from chimpanzees.

The Examiner admits that “one of skill in the art would recognize that a unique expression (e.g., overexpression, underexpression, or expressed at some point while absent during some point) of a particular nucleic acid for a particular phenotype, condition or state would have an immediate applicable utility” *Id.* at page 10, emphasis added. The Examiner, however, states that “the microarray of the claimed invention does not disclose such knowledge.” *Id.* The Appellants respectfully disagree because the nucleic acids of the claimed microarray were expressed during anthesis, which is a “particular phenotype, condition or state”. Using the Examiner’s own admission, the nucleic acids “have an immediate applicable utility”.

Moreover, the Examiner appears to focus on the utility of the individual nucleic acid sequences contained on the claimed microarray. Claims must be considered as a whole in

determining compliance with § 101. *Diamond v. Diehr*, 450 U.S. 175, 188, 209 U.S.P.Q. 1, 9 (1981). It is inappropriate to dissect claims and consider some elements while ignoring others.

*Id.* The rejection of the claims continues to focus on the function of the proteins encoded by individual nucleic acid sequences recited in the Markush group on the claimed microarray. The Appellants respectfully submit that they are not claiming recited nucleic acid sequences in the abstract. The Appellants have disclosed nucleic acid sequences obtained from maize. The claims however are not limited to the nucleic acid sequences, but are directed as a whole to microarrays that comprise, *inter alia*, various nucleic acid sequences selected from the recited Markush group. Accordingly, the Examiner's arguments that the patentability of the claims is based on the utility of individual nucleic acid sequences alone is improper.

The Examiner responds by stating "that whether the mere isolation of expressed nucleic acid sequences (ESTs) in an collective form, absent a substantial utility, is the issue central to determining whether the claims meet the utility requirement." *Final Office Action* at page 8. This statement provided validation to the Appellants' position that the Examiner continues to be focused on the nucleic acid sequences, rather than on the claimed invention as a whole. Indeed, the Examiner pejoratively dismisses the claimed invention as "the mere isolation of expressed nucleic acid sequences (ESTs) in an collective form". *Id.*, emphasis added. The Examiner goes on to state that "(t)he claims are drawn to a product. The product, as the claims recite, are defined by SEQ ID Numbers and the patentability is based on the SEQ ID Numbers." *Id.* at page 12. This statement further reinforces the Appellants' position that the Examiner is not addressing the claimed invention as a whole.

Moreover, the Office has acknowledged that microarrays in general have a specific and substantial utility by way of their “utility for being able to analyze a plurality of nucleic acid samples simultaneously.” *Examiner’s Answer* dated May 23, 2003 at page 8 and *see*, Board Decision mailed November 22, 2005 at page 10. The claimed microarrays similarly have the ability to analyze a large number of nucleic acid molecules in a sample simultaneously, for example, for the presence of maize nucleic acid sequences expressed during anthesis within the sample. The skilled artisan would recognize that such microarrays can be useful in identity preservation programs.

In addition, the Office has acknowledged that the in the Fodor and Pirrung patents, “the skilled artisan is free to select the relevant reagent (*e.g.*, nucleic acid) of their choice to attach to the array.” Board Decision at page 10. Claims 8 and 12 to 27 similarly allow the skilled artisan to design or customize a particular microarray tailored to the specific requirements of the artisan. The claimed microarrays can be tailored to a given set of requirements while providing sequences selected from the recited Markush group that can act, for example, as a control to test technical performance of the array.

The “basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form.” *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). The Appellants have met this part of the bargain – the present specification discloses microarrays which, in their current form, provide at least one specific benefit to the public, for example, use to analyze biological samples for the presence of

maize nucleic acid sequences. *See, e.g., Specification* at page 59, lines 18 to 24. This benefit is specific, not vague or unknown, and it is a “real world” or substantial benefit.

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose “that an invention is useful to the public as disclosed in its current form.” *Id.* at 1371. Second, the Court further noted that the specification “also show that that claimed invention can be used to provide a well-defined and particular benefit.” *Id.* The Appellants have provided microarrays which are shown in the specification to be useful in analyzing biological samples for the presence of maize nucleic acid sequences. Such a use is sufficient to satisfy the utility standard. *Id.*

The specification discloses specific and substantial uses for the claimed microarrays, including use to analyze biological samples for the presence of maize nucleic acid sequence homologues (*see, e.g., Specification* at page 59, line 18 through page 60, line 26, and page 21, lines 11 to 17) and in high-throughput monitoring of gene expression in a corn plant (*see, e.g., Specification* at page 59, line 25 through page 60, line 16 and page 61, lines 4 to 10). Moreover, because one skilled in the art may design a microarray comprising a substrate with a variety of molecules characterized by different sequences from the recited Markush group, *see, e.g., claim 8*, the claimed microarrays may be varied or customized to identify or screen for a particular nucleic acid molecule or molecules as designated by the designer. *See, e.g., Petition under 37 C.F.R. § 1.144, filed January 10, 2003, at pages 7 to 10.* The Examiner argues that this utility, like many of the asserted utilities, is not specific or substantial. *Final Office Action* at page 5, but

does not provide any support (legal or factual) for the proposition that screening large populations of nucleic acids using the claimed microarrays is not a legally sufficient utility.

One of ordinary skill in the art would recognize that the claimed microarrays have utility, for example, to analyze biological samples for the presence of maize nucleic acid sequences or for high-throughput monitoring of gene expression in a corn plant. These utilities are immediately apparent for the claimed microarrays without further research. The claimed microarrays have been asserted to be useful in analyzing biological samples for the presence of maize molecules and for high-throughput monitoring of gene expression in a corn plant. These utilities provide a well-defined and particular benefit, *e.g.*, to identify maize nucleic acid molecules in a sample, and these utilities are immediately useful to the public as disclosed in their current form. Accordingly, the assertion of the use of the claimed microarrays to analyze such samples satisfies the utility requirement of 35 U.S.C. § 101.

The claimed microarrays have been asserted to be useful in analyzing biological samples for the presence of maize molecules and for high-throughput monitoring of gene expression in a corn plant. These utilities provide a well-defined and particular benefit, *e.g.*, to identify maize nucleic acid molecules in a sample, and these utilities are immediately useful to the public as disclosed in their current form. The Appellants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

In conclusion, the Appellants respectfully submit that the assertion of the uses of the claimed microarrays fully satisfy the utility requirement of 35 U.S.C. §§ 101 and 112, first paragraph. Therefore, the Appellants respectfully request that the Board reverse the rejection of claims 8 to 10 and 12 to 27 under 35 U.S.C. §§ 101 and 112, first paragraph.

### **C. The Claimed Microarrays Are Enabled by the Specification**

The enablement of the claimed microarrays has been challenged. Claims 8-10 and 12-27 were rejected as not enabled by the specification, because the recited nucleic acid molecules allegedly lack utility and therefore cannot be enabled. *Final Action* at page 17. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that “the enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), quoting *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. See *In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) (“pure conjecture” does not substantiate rejection for lack of enablement).

### **D. The Specification Provides An Adequate Written Description of the Claimed Invention**

The Examiner rejected pending claims 8 to 10 and 12 to 27 under 35 U.S.C. § 112, first paragraph, as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention”. *Final Office Action* at page 17.

The Examiner admits that the SEQ ID Numbers of the Markush group in the claims meet the written description provision of 35 U.S.C. § 112, first paragraph. *Final Office Action* at page 18. The Examiner argues, however, that

claims 8-10 and 12-27 recite nucleic acid (*sic*) comprising the claimed SEQ ID Numbers. Because it is not apparent from the specification that the claimed SEQ ID Numbers contain a full open reading frame, the claimed nucleic acids of SEQ ID Numbers read on cDNAs of full open reading frame. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompasses by the claim.

*Id.* at page 18. The Examiner goes on to add “the full breadth of the claims not only embrace the above-discussed embodiment [*i.e.*, a microarray comprising the recited nucleic acid molecules] but also [a] microarray “comprising at least 250 nucleotides” that are complimentary [*sic*] to a collection of SEQ ID Numbers. Hence, the full-breadth of the claims read on microarray comprising full-length gene which are complementary to SEQ ID Numbers, the genes of which comprising additional sequences in addition to the 250 complementary nucleotides.” *Id.* at page 20.

In short, the Examiner argues that because the specification does not explicitly state that the SEQ ID NOS do not contain full open reading frames, the claimed nucleic acids of SEQ ID NOS must automatically read on cDNAs with full open reading frames, and “(t)he specification clearly demonstrates that the nucleic acid of the SEQ ID Numbers are ESTs, and no evidence is shown that they have identified the entire open-reading frame of from which these ESTs are derived from (*sic*).” *Id.* The Appellants respectfully disagree. The claimed microarrays do not recite open reading frames, and thus need not describe them. Moreover, the skilled artisan would be able to identify open reading frames within the recited sequences using methods known in the

art. The Appellants have fully described each SEQ ID NO by setting forth its nucleotide sequence.

In addition, the Examiner argues that because the claims use the transitional phrase “comprising” there is insufficient written description in the specification. This cannot be a proper basis for a written description rejection of a “comprising” claim. If it were, every “comprising” claim ever written would be invalid for failing to describe every nuance of the claimed invention – and the Examiner appears to assert that each nucleic acid molecule within the genus must be described by its complete structure. Not only are these assertions unfounded, the specification demonstrates to one skilled in the art that the Appellants were in fact in possession of the claimed microarrays comprising the claimed genera of nucleic acid molecules.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that the Appellants had possession a microarray comprising nucleic acid sequences selected from the group consisting of SEQ ID NOs: 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc., and their complements, and therefore, the claimed invention.

The Appellants have provided the nucleotide sequences recited by the claims, *e.g.*, SEQ ID 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc., and have disclosed microarrays comprising such sequences, and have thus established possession of the claimed invention. Moreover, the present application describes more than just microarrays including the nucleotide sequences required by the claims. For example, it describes vectors comprising the claimed nucleic acid molecules, *see, e.g.*, *Specification* at page 67, line 14 through page 74, line 11, as well as plants transformed by the nucleic acid molecules of the present invention. *See, e.g.*, *Specification* at page 74, line 16 to page 82, line 24). Thus, the fact that the claims at issue are intended to cover microarrays comprising nucleic acid molecules that include the recited sequences joined with additional sequences, or complements of the recited sequences does not mean that the Appellants were any less in possession of the nucleic acid molecules of the claimed microarrays.<sup>1</sup> It is well-established that use of the transitional term “comprising” leaves the claims “open for the inclusion of unspecified ingredients even in major amounts.” *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the claimed microarrays and the nucleic acid sequences of the claimed microarrays. For example, it describes how to make the nucleotide sequences and the libraries from which they were originally purified (specification at

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<sup>1</sup> If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsius verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

page 33, line 6 through page 39, line 25, and Examples 1 and 2). In addition, one of ordinary skill in the art has the ability to make and use the claimed microarrays based on the disclosure of the present specification, as well as envision a nucleic acid molecule that is complementary to any of the nucleic acid molecules of the claimed microarrays. Furthermore, the addition of extra nucleotides or detectable labels to the sequences present on the claimed microarrays is readily envisioned by one of ordinary skill in the art upon reading the present specification,<sup>2</sup> in particular at page 17, lines 20 to 24 (describing sequences with labels to facilitate detection); at page 62, line 8 through page 63, line 2 (describing site-directed mutagenesis of nucleic acid molecules); and at page 86, line 22 to page 87, line 3 (citing references describing the construction, manipulation and isolation of macromolecules). Moreover, it is well established that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (CCPA 1981)).

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) as recently amplified by *Capon v. Eshhar*, 418 F.3d 1349, 76 U.S.P.Q. 1078 (Fed. Cir. 2005). The Appellants have satisfied that test for written description. The claimed microarrays comprise combinations or collections of several genera of nucleic acid molecules. Each genus of nucleic

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<sup>2</sup> It is established patent jurisprudence that Applicants need not teach “conventional and well-known genetic engineering techniques.” *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

acid molecules on the claimed microarray comprise sequences that are complementary to at least one particular enumerated nucleotide sequence, for example, SEQ ID NOs: 5776, 5781, 5782, 5783, 5785, 5787, 5800, 5804, 5815, 5818, etc. The Appellants have disclosed common structural features for each genus of nucleic acid molecules, for example, SEQ ID NO: 5776. The respective common structural feature (*i.e.*, the complement or complements to a nucleotide sequence or sequences recited in the present claims) is shared by every nucleic acid molecule which may be included in a claimed microarray comprising a particular nucleic acid molecule; and the nucleic acid sequence of that nucleic acid molecule distinguishes the members of that genus of nucleic acid molecules from non-members.

One skilled in the art would clearly know if a microarray comprises a substrate with a surface comprising 1000 nucleic acid molecules or more where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising any one or more of the recited nucleotide sequences. The fact that a nucleic acid molecule may comprise additional sequences, variations, or a full-length cDNA is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

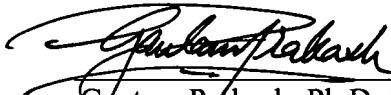
In sum, the specification demonstrates that the Appellants had possession of the claimed microarrays, and have provided an adequate description of the claimed genera of microarrays comprising nucleic acid molecules that are complementary to a nucleic acid molecule comprising one of the recited SEQ ID NOs. Therefore, the specification fully satisfies the written description requirement of 35 U.S.C. § 112, first paragraph, and the Appellants respectfully

request that the Board reverse the rejection of claims 8 to 10 and 12 to 27 under 35 U.S.C. § 112,  
first paragraph.

**CONCLUSION**

In view of the foregoing, the Appellants respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



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**CLAIMS APPENDIX**

Claim 8. A microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID

NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, and SEQ ID NO: 6181, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 9. A microarray according to claim 8 where at least 75% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from said group.

Claim 10. A microarray according to claim 8 where at least 95% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from said group.

Claim 11. (Canceled)

Claim 12. The microarray according to claim 8, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 13. The microarray according to claim 12, wherein said nucleic acid molecules are derived from LIB189.

Claim 14. A microarray comprising a substrate with a surface comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised of different sequences and at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO:

5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, SEQ ID NO: 6181 SEQ ID NO: 6188, SEQ ID NO: 6195, SEQ ID NO: 6196, SEQ ID NO: 6205, SEQ ID NO: 6211, SEQ ID NO: 6212, SEQ

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Claim 15. The microarray according to claim 14, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 16. The microarray according to claims 15, wherein said nucleic acid molecules are derived from LIB189.

Claim 17. The microarray according to claim 14, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 18. A microarray comprising a substrate with a surface having at least 1000 nucleic acid molecules where more than 10% of said nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ

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Claim 19. The microarray according to claim 18, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 20. The microarray according to claim 19, wherein said nucleic acid molecules are derived from LIB189.

Claim 21. The microarray according to claim 18, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 22. A microarray comprising nucleic acid sequences obtained from maize, wherein said microarray comprises a substrate with a surface having at least 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences

selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO: 5937, SEQ ID NO: 5939, SEQ ID NO: 5941, SEQ ID NO: 5944, SEQ ID NO: 5945, SEQ ID NO: 5950, SEQ ID NO: 5955, SEQ ID NO: 5960, SEQ ID NO: 5961, SEQ ID NO: 5963, SEQ ID NO: 5964, SEQ ID NO: 5968, SEQ ID NO: 5973, SEQ ID NO: 5974, SEQ ID NO: 5991, SEQ ID NO: 5994, SEQ ID NO: 5999, SEQ ID NO: 6000, SEQ ID NO: 6001, SEQ ID NO: 6005, SEQ ID NO: 6006, SEQ ID NO: 6007, SEQ ID NO: 6011, SEQ ID NO: 6017, SEQ ID NO: 6018, SEQ ID NO: 6022, SEQ ID NO: 6023, SEQ ID NO: 6026, SEQ ID NO: 6030, SEQ ID NO: 6033, SEQ ID NO: 6042, SEQ ID NO: 6046, SEQ ID NO: 6059, SEQ ID NO: 6063, SEQ ID NO: 6065, SEQ ID NO: 6066, SEQ ID NO: 6089, SEQ ID NO: 6091, SEQ ID NO: 6098, SEQ ID NO: 6106, SEQ ID NO: 6107, SEQ ID NO: 6110, SEQ ID NO: 6117, SEQ ID NO: 6121, SEQ ID NO: 6124, SEQ ID NO: 6131, SEQ ID NO: 6137, SEQ ID NO: 6141, SEQ ID NO: 6144, SEQ ID NO: 6145, SEQ ID NO: 6147, SEQ ID NO: 6154, SEQ ID NO: 6167, SEQ ID NO: 6168, SEQ ID NO: 6170, SEQ ID NO: 6173, SEQ ID NO: 6178, SEQ ID NO: 6181 SEQ ID NO: 6188, SEQ ID NO: 6195, SEQ ID NO:

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SEQ ID NO: 8631, SEQ ID NO: 8632, SEQ ID NO: 8639, SEQ ID NO: 8644, and SEQ ID NO: 8665.

Claim 23. The microarray according to claim 22, wherein said nucleic acid molecules are derived from maize genotype RX601.

Claim 24. The microarray according to claim 23, wherein said nucleic acid molecules are derived from LIB189.

Claim 25. The microarray according to claim 22, wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences.

Claim 26. A substrate containing nucleic acid molecules obtained from maize, wherein said substrate comprises a surface having 1000 nucleic acid molecules where more than 10% of the nucleic acid molecules comprise nucleic acid sequences complementary to at least 250 nucleotides of more than 100 different nucleic acid sequences selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845, SEQ ID NO: 5849, SEQ ID NO: 5850, SEQ ID NO: 5851, SEQ ID NO: 5856, SEQ ID NO: 5859, SEQ ID NO: 5863, SEQ ID NO: 5868, SEQ ID NO: 5871, SEQ ID NO: 5874, SEQ ID NO: 5875, SEQ ID NO: 5877, SEQ ID NO: 5893, SEQ ID NO: 5896, SEQ ID NO: 5901, SEQ ID NO: 5908, SEQ ID NO: 5909, SEQ ID NO: 5920, SEQ ID NO: 5922, SEQ ID NO: 5926, SEQ ID NO: 5928, SEQ ID NO: 5929, SEQ ID NO: 5931, SEQ ID NO: 5936, SEQ ID NO:

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Claim 27. A microarray for high-throughput monitoring of gene expression in a corn plant, where said microarray comprises a substrate with an array of at least 1000 oligonucleotide probes that hybridize to at least 1000 different nucleic acid molecules expressed by corn plant genes where at least 10% of the nucleic acid molecules are at least about 250 nucleotide residues and complementary to a molecule comprising a sequence selected from the group consisting of SEQ ID NO: 5776, SEQ ID NO: 5781, SEQ ID NO: 5782, SEQ ID NO: 5783, SEQ ID NO: 5785, SEQ ID NO: 5787, SEQ ID NO: 5800, SEQ ID NO: 5804, SEQ ID NO: 5815, SEQ ID NO: 5818, SEQ ID NO: 5821, SEQ ID NO: 5823, SEQ ID NO: 5828, SEQ ID NO: 5830, SEQ ID NO: 5832, SEQ ID NO: 5836, SEQ ID NO: 5838, SEQ ID NO: 5840, SEQ ID NO: 5845,

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**EVIDENCE APPENDIX**

None

**RELATED PROCEEDINGS APPENDIX**

1. BPAI Appeal No. 2005-1340; and
2. *In re Fisher*, 412 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005).